



DEPARTMENT OF HEALTH & HUMAN SERVICES

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TO: Division of Human Subject Protections, OPRR

FROM: Director, Division of Human Subject Protections, OPRR

SUBJECT: IRB Approval Periods and Continuing Review of Research

As you know, Department of Health and Human Services regulations at 45 CFR 46.109(e) require that Institutional Review Boards (IRBs) conduct continuing review of research not less than once per year. The regulations make no provision for any grace period extending the conduct of research beyond the expiration date of IRB approval. Continuing review and re-approval of research must occur on or before the one year anniversary of the initial IRB approval date.

OPRR recognizes the logistical advantages in keeping the IRB approval period (e.g., July 1 through June 30) constant from year to year throughout the life of each project. However, such a system necessarily results in continuing review approvals which predate the beginning of the next approval period. While OPRR understands the complexities involved in administering a large number of protocols, OPRR expects that institutions will make every effort to yoke as closely as possible (a) the receipt by the IRB of continuing review materials, (b) the review of those materials by the convened IRB, and (c) the beginning of the subsequent approval period. OPRR expects that any temporal lag between the date of IRB review and the beginning of the approval period will be as brief as possible, and in no case exceed 30 days. OPRR strongly encourages institutions to develop administrative procedures and computer tracking systems which make such a lag unnecessary.

However, understanding that such a lag is sometimes unavoidable, OPRR provides the following concrete example of an acceptable system:

- (i) With an initial IRB review and approval on 01/19/2000, the initial approval period begins on 01/19/2000 and ends on 01/18/2001.
- (ii) With the second year IRB review and approval occurring on 01/03/2001, it is acceptable to designate an approval period of 01/19/2001 to 01/18/2002 (i.e., keeping the actual month and day of the approval period constant from year to year).
- (iii) With the third year IRB review and approval occurring on 12/30/2001, it is acceptable to designate an approval period of 01/19/2002 to 01/18/2003.

The DHSP Director should be consulted should Coordinators require assistance in applying these guidelines to specific situations.

J. Thomas Puglisi, Ph.D.

Attachment

cc: Dr. Gary Ellis
Dr. Melody Lin
Ms. Michele Russell-Einhorn